

Raymond S. Hartman, Ph.D. CONFIDENTIAL
Boston, MA

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<p style="text-align: right;">866</p> <p>1 market power? Is that what you're saying?</p> <p>2 MR. SOBOL: Objection.</p> <p>3 A. No. I just -- I made a comment about</p> <p>4 what generated market power on the part of</p> <p>5 physicians, and the --</p> <p>6 Q. Well, why are payers willing to let</p> <p>7 physicians earn up to 30 percent on drugs in your</p> <p>8 view?</p> <p>9 A. In my view, it reflects what Mr. -- what</p> <p>10 Mr. Young had stated: That in prior to 1992,</p> <p>11 going into 1992, Medicare essentially reimbursed</p> <p>12 on a cost basis, and the cost was assumed to be</p> <p>13 more or less AWP, and that -- and as -- as the</p> <p>14 transition went into more focus on reimbursement</p> <p>15 under Medicare, there was a realization that</p> <p>16 reimbursement at AWP or some percent -- and then</p> <p>17 the percentage off of AWP and the private third-</p> <p>18 party payers, that allowed the doctors to earn</p> <p>19 what was the retail margin, more or less.</p> <p>20 So there is a small margin that the</p> <p>21 doctors were earning as part of their</p> <p>22 administering the drugs, and I don't think that</p>	<p style="text-align: right;">868</p> <p>1 look at the Dyckman figure 13 -- oh, no, -- oh,</p> <p>2 yes, that is right.</p> <p>3 So if I am on average, this average is</p> <p>4 about 97 percent of AWP, and so for the aggregate</p> <p>5 measure of what the payers are willing to -- have</p> <p>6 been reimbursing or the profits that are earned on</p> <p>7 aggregate by the providers, at some aggregate</p> <p>8 measure, it is 97 percent -- 95 -- 97.5 percent</p> <p>9 AWP less ASP, over ASP, so it is a little less</p> <p>10 than 30 percent.</p> <p>11 Q. Well, let's take a contract where the</p> <p>12 reimbursement rate is AWP.</p> <p>13 A. That's fine. Then we are at 30 percent.</p> <p>14 Q. In that situation, you would agree with</p> <p>15 me that the provider is willing to -- I am sorry -</p> <p>16 - that the payer is willing to enable the provider</p> <p>17 to earn a profit of 30 percent over the</p> <p>18 acquisition cost of the drug; correct?</p> <p>19 MR. SOBOL: Objection.</p> <p>20 A. In that world, the provider is allowed</p> <p>21 to drive the speed limit.</p> <p>22 Q. Right. And the payer is agreeing with</p>
<p style="text-align: right;">867</p> <p>1 was a -- they weren't thinking about market power</p> <p>2 at that point or -- whatever they -- the</p> <p>3 realization of the market power was on the part of</p> <p>4 the manufacturers in terms of increasing the</p> <p>5 spread.</p> <p>6 Q. But that margin is 30 percent; right?</p> <p>7 A. With the --</p> <p>8 MR. SOBOL: Objection.</p> <p>9 A. No.</p> <p>10 Q. In other words, in your but-for world,</p> <p>11 assuming a payer understood what ASP was and sat</p> <p>12 down with a provider and negotiated a contract,</p> <p>13 that payer should be willing to reimburse that</p> <p>14 provider at a rate that is 30 percent above the</p> <p>15 ASP; correct?</p> <p>16 MR. SOBOL: Objection.</p> <p>17 A. . When we look at the Medpac survey, we</p> <p>18 find that different payers have themselves</p> <p>19 different amounts of clout in the negotiations,</p> <p>20 such that they are willing to -- they agree to</p> <p>21 reimburse AWP less 15 percent, 85 percent of AWP,</p> <p>22 and some are up to AWP plus 10 percent. If we</p>	<p style="text-align: right;">869</p> <p>1 the provider, basically it is okay with me if you</p> <p>2 earn 30 percent on these drugs; that's why I am</p> <p>3 setting the AWP -- I am sorry -- that is why I am</p> <p>4 setting the reimbursement rate at AWP; correct?</p> <p>5 A. The -- that is assuming the provider</p> <p>6 knows -- the payer knows the ASP. The payer until</p> <p>7 2005 did not.</p> <p>8 Q. But I want you to --</p> <p>9 A. But, you know, there is some -- the</p> <p>10 providers up until that point saw some of these</p> <p>11 anecdotal information, but that would have said to</p> <p>12 me prior to 2005 that the provider -- the payer</p> <p>13 thought, well, the guy is earning the retail</p> <p>14 margin plus some, so, you know, could be making 10</p> <p>15 percent, 15 percent above ASP, 5 percent.</p> <p>16 Q. Well, assume with me that the payer knew</p> <p>17 what the ASP was --</p> <p>18 A. Okay.</p> <p>19 Q. -- and the payer agreed to reimburse the</p> <p>20 provider at AWP. In that scenario, the payer</p> <p>21 would be agreeing that the provider could earn a</p> <p>22 margin of 30 percent; correct?</p>

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1 A. In that -- in that example, the payer
2 agrees to the upper bound of the expectations that
3 I have found in the data that had been used for my
4 -- for the liability yardstick in my December
5 declaration.

6 Q. And that 30 percent would essentially
7 reflect the providers' market power in that
8 particular negotiation; correct?

9 A. No. I mean they are also negotiating
10 the fees, so that there are other things being
11 negotiated. Money being paid to the provider is
12 not just the amount on the drugs. There is fees,
13 and there is -- there is other things being
14 negotiated.

15 Q. So you can't really analyze the impact
16 of the spread in a situation like this without
17 looking at all of the other aspects of the
18 contractual relationship between the payer and the
19 provider? Is that what you're saying?

20 A. No.

21 Q. What is your definition of market power?

22 A. Market power can -- the traditional

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1 textbook definition of market power in thinking
2 about a monopolist is that, or a small group of
3 producers, is that there is essentially enough
4 control of production in that market that there is
5 the power to raise price above cost, and that's a
6 textbook definition of --

7 Q. And in the particular --

8 A. -- one of --

9 Q. -- example I just recited where the
10 provider has been reimbursed at AWP, that provider
11 has sufficient market power to raise the price to
12 30 percent above cost; correct?

13 MR. SOBOL: Objection to the form.

14 A. We've -- the -- we have already
15 discussed -- I mean right now we're talking about
16 a variety of different notions of market power. I
17 mean there is -- I have given you the textbook
18 example, but another notion of having power to
19 influence the market or market power is to move
20 market share, and that is something that is --
21 that is retained and that reflects the physician's
22 position and the providers' position in the

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1 provider -- in the world of providers.

2 So that, that type of market power
3 relative to the -- his clients, the doctors'
4 clients, the patients, and what they are going to
5 end up paying for, that -- that is a market power
6 that -- it -- we're -- is a little bit off what
7 you're trying to get at here. You are talking
8 about the payers trying to pay them something or -
9 - I'm not talking -- the market power I am talking
10 about is not in negotiating with the payer right
11 now. I am talking about the ability to move
12 patients from one drug to another, and that power,
13 and that right now is not -- that's - - we're not
14 -- they're not -- that's not being -- I am not
15 sitting down as a provider and negotiating with a
16 payer just based on that notion.

17 Q. Are you saying that providers have no
18 market power in their negotiations with payers?

19 A. I would say that there is some providers
20 that have -- I would say that there is variation
21 in that market power.

22 Q. In the situation where the provider is

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1 able to earn a profit of 30 percent over ASP, how
2 much of that 30 percent is attributable to the
3 providers' market power?

4 A. The revealed negotiations of the
5 implications of market power and the ability in
6 the negotiations to effectuate reimbursement and,
7 therefore, demonstrate market power is shown in
8 Exhibit 13 of the Dyckman report where the
9 percentage off of AWP ranges from 85 to 115. So
10 this is merely one measure of what the ability is
11 of a provider to take advantage of whether it is a
12 large oncology group or just a single
13 practitioner. The service fees and other things
14 are also part of that. So you are -- that
15 question can't be answered only looking at drug
16 costs.

17 Q. So but you are saying that some part of
18 that 30 percent would be attributable to the
19 provider's market power? You just haven't figured
20 out what it is yet; correct?

21 MR. SOBOL: Objection.

22 A. It is -- the question is so -- I don't -

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<p style="text-align: right;">874</p> <p>1 - I don't understand what you mean by parsing that 2 and attributing part of it. I -- I -- I guess I 3 don't really understand what you're getting at. 4 Q. Is any part of it attributable to the 5 provider's market power? 6 A. Well, one can certainly say that in a 7 negotiation where there is some understanding of 8 what acquisition costs are and that is -- there is 9 asymmetric information. Up to 2005, apparently 10 only the provider knew what the ASP was, except 11 for anecdotal information in Barron's and reports 12 here and there, but as providers sat down and 13 negotiated with payers, they were able to extract 14 -- they knew what their ASP was for all their 15 drugs, and they were able -- some were able to 16 say, look, I want to be reimbursed AWP plus 15 -- 17 plus 15 percent. Well, they were in a stronger 18 position to negotiate in that bilateral 19 negotiation, and they revealed power. 20 Now that is not really the classic 21 definition of market power, and I don't know 22 really what you're getting at with market power</p>	<p style="text-align: right;">876</p> <p>1 analysis of that. 2 MR. EDWARDS: Time for a short break? 3 MR. SOBOL: Okay. 4 THE VIDEOGRAPHER: The time is 4:14. 5 This is the end of cassette number 3. We are off 6 the record. 7 (Recess taken at 4:14 p.m.) 8 (Recess ended at 4:28 p.m.) 9 THE VIDEOGRAPHER: The time is 4:28 p.m. 10 This is the beginning of cassette number 4 in the 11 deposition of Mr. Raymond Hartman. We are on the ~ 12 record. 13 BY MR. EDWARDS: 14 Q. Dr. Hartman, I want to turn to that 15 portion of your report that deals with the damage 16 yardstick for Medicare, and I guess in your 17 supplemental report, it is the yardstick for 18 liability and damages, and that is the yardstick 19 that you have characterized as, I think, zero by 20 statute in your previous testimony; is that 21 correct? 22 A. I've -- I've used the shorthand that the</p>
<p style="text-align: right;">875</p> <p>1 and percentages of this related to that. We are 2 talking about the ability in a negotiation to come 3 up with some -- some relationship of what your 4 reimbursement is going to be, period, and that is 5 based on -- historically based on the providers 6 knew what their ASPs were; Medicare and the payers 7 did not. They came to understand what they were. 8 But this distribution here indicates the 9 ability of payers -- of providers to say, "I want 10 a higher -- no matter what my ASP is, I want more 11 money to be reimbursed to me from you," and they 12 get it, so that is power. 13 (Pointing to Exhibit Hartman 020.) 14 A. That's an ability to take advantage of 15 the position, your market position, and increase 16 your price. 17 Q. Have you considered whether some payers 18 don't care about the cost of individual drugs to 19 the provider? All they care about is the bottom- 20 line profitability of the provider? 21 A. I would -- I haven't -- you know, I 22 could speculate, but I haven't done any detailed</p>	<p style="text-align: right;">877</p> <p>1 spread would be zero in that case. That 2 essentially that the re -- yes. That's -- yes. 3 Q. And the statute is what statute? 4 A. Well, it is an unfolding set of statutes 5 and revisions that are laid out in footnote 13, 6 which has the sources within the CFR regulations 7 of what the reimbursement under Medicare would be, 8 and for single-source and multi-source drugs, so 9 it essentially is the basis for wherever I cite a 10 spread or a calculation for damages, it is based 11 on the Medicare statutes as they are summarized in 12 footnote 13. 13 Q. For the period 1992 through 1997, are 14 you talking about a statute or a regulation? 15 A. I'm -- it is my understanding it is a 16 regulation. I -- not being a lawyer, I kind of 17 think of them as the same, and actually, I almost 18 thought -- I thought Judge Saras referred to them 19 as statutory enablement, too. 20 Q. Are you familiar with the regulation? 21 A. You know, I have skimmed parts of it. I 22 am familiar with these sections of it. I mean</p>

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1 there is a lot of paper involved with every
2 revision.
3 MR EDWARDS: What I want to do is mark
4 as Exhibit Hartman 038 a copy of an excerpt of the
5 regulation, which is 45 CFR -- no -- it is 42 CFR.
6 I believe it is 405.

7 THE WITNESS: .517 maybe.
8 (Excerpt from Federal Register
9 marked Exhibit Hartman 038 for identification.)

10 BY MR. EDWARDS:

11 Q. Which portion of the regulation do you
12 rely on? And let me just say that we have
13 provided a copy of the actual regulation as it
14 appears in the Federal Register, but it is --

15 A. Blurry.

16 Q. -- hard to read, and there is a typed-
17 up version attached to it.

18 A. I thought you just gave me -- I thought
19 it was like the dribble glass. This is the
20 dribble exhibit that I can't really read. I mean I
21 am having trouble.

22 Q. Why don't you look at the last page of

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1 that proposition is established?

2 A. I would frame it -- I am -- I am --
3 maybe the answer is yes to that, but let me just
4 see, make sure.

5 The statute is what it is, and it says
6 how reimbursement should be paid under Medicare
7 claims, and given that, that's my understanding of
8 what the regulations are and how reimbursement
9 should have been paid by Medicare, and that just -
10 - that exists. I -- I then go and do analyses of
11 thresholds of liability to see whether drugs are
12 applicable to evaluating what the implications of
13 this alternative reimbursement strategy --
14 reimbursement regulation is if the reimbursement
15 was not at the acquisition cost.

16 Q. So you are offering an opinion on the
17 proper interpretation of this regulation?

18 A. I am offering an interpretation on --
19 that is nothing more than my reading of what --
20 what you have in a box there about what -- what
21 the reimbursement rate should be. That it is going
22 to be, as I have stated in that footnote, payment

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1 this document, Exhibit Hartman 038.

2 (Witness complying.)

3 A. Okay. And?

4 Q. There is a reference to Section 405.517.
5 Is that the regulation that you rely on?

6 A. The last page of all of the typed pages
7 or -- oh, I see here. Okay. 405.517?

8 (Pause.)

9 (The witness viewing Exhibit
10 Hartman 038.)

11 A. That is correct. That is what is
12 summarized in footnote 12 for reimbursement
13 covering the period '92 through 1997.

14 Q. Now you admitted at your last deposition
15 that you are not an expert on Medicare regulations
16 and you don't have a law degree. Has that
17 changed?

18 A. No.

19 Q. Are you expressing an expert opinion
20 that it is zero by statute, or are you simply
21 assuming that that will be proven by other means,
22 and you are just running the numbers, assuming

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1 for a drug is based on the lower of the estimated
2 acquisition cost or the national average wholesale
3 price of the drug. That -- and that's what it
4 says here. And then for multi- source drugs, the
5 payment is based on the lower of the estimated
6 acquisition cost or the wholesale price for
7 purposes -- for that period of time. It is
8 defined as median price for all sources of the
9 generic form of the drug, so.

10 Q. What is it that qualifies you to offer
11 that opinion?

12 A. My ability to read.

13 Q. Nothing more?

14 A. That's right.

15 Q. So anybody could offer this opinion?

16 A. If -- I am assuming this is how
17 reimbursement was to be made, and because I am
18 reading it here in the regulations, and that's --
19 that's as far as my opinion goes.

20 Q. This opinion doesn't depend on your
21 expertise as an economist; correct?

22 A. That's correct.

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<p style="text-align: right;">882</p> <p>1 Q. You did not take any courses on 2 statutory interpretation in graduate school; 3 correct? 4 A. No. 5 Q. Now this regulation actually says that 6 estimated acquisition cost and average wholesale 7 price are two different things, doesn't it? 8 A. I'm sorry. Could you say that again? I 9 was -- it -- it? 10 Q. This regulation says, "Payment for a 11 drug described in paragraph A of this section is 12 based on the lower of the estimated acquisition 13 cost or" -- and it uses the word "or" -- "the 14 national average wholesale price of the drug." 15 Correct? 16 A. That's correct. 17 Q. And the use of "or" in that context 18 suggests that estimated acquisition cost and AWP 19 are two different things; correct? 20 A. They -- they could -- they could be 21 equal to the same thing, but it is not -- but it 22 doesn't -- it says "or," so it is the lesser of.</p>	<p style="text-align: right;">884</p> <p>1 A. Well, it's -- the -- the reimbursement 2 rate is not zero. The spread, the measured 3 spread, would be zero. The -- essentially what 4 the -- what this is saying is, "Look, if you are 5 going to reimburse, you are going to reimburse at 6 AWP or the estimated acquisition cost," and the 7 estimated acquisition cost was out there. It is 8 just the surveys weren't done to inform Medicare 9 what it was. 10 Q. But your opinion that it is zero by 11 statute is based on the estimated acquisition cost 12 part of this regulation; correct? 13 A. My calculation of damages, if a -- in my 14 December report, if a drug exceeds a threshold of 15 liability, of the 30 percent, then there is a 16 calculation of what are the implications of the 17 deviation of a reimbursement being at AWP when by 18 statute it should have been by -- at the estimated 19 acquisition cost. 20 Q. You are assuming that estimated 21 acquisition cost, if it had been implemented, 22 would have yielded a spread of zero; correct?</p>
<p style="text-align: right;">883</p> <p>1 Q. The lesser of, so it is two different 2 things; correct? 3 A. One or the other. Yes. Two different 4 measures. 5 Q. And as far as you know, Medicare 6 understood that estimated acquisition cost and AWP 7 were two different things; correct? 8 A. That's my understanding. 9 Q. The regulation goes on to say that "The 10 estimated acquisition cost is determined based on 11 surveys of the actual invoice prices paid for the 12 drug." 13 Do you know whether those surveys were 14 ever conducted? 15 A. It's my understanding they were not. 16 Q. So the estimated acquisition cost part 17 of this regulation was never implemented; correct? 18 A. Those surveys were not -- were not done. 19 Q. So you are basing your opinion that the 20 proper reimbursement rate under Medicare is zero 21 by statute on a provision of a regulation that was 22 never implemented?</p>	<p style="text-align: right;">885</p> <p>1 A. The -- 2 Q. In other words, EAC would have equalled 3 ASP as defined in your December 15th report? 4 A. EAC would be equal to the estimated -- 5 the -- it is also referred to as the average 6 acquisition cost in some -- in some of the 7 descriptions of this. 8 But the average acquisition cost is the 9 average sales price to the set of providers that 10 we're talking about, and to the extent that the 11 AWP exceeds that average sale price, under this 12 payment regulation I calculate the extent of that 13 spread as a measure to which the reimbursement was 14 greater than the estimated acquisition cost. 15 Q. Well, Medicare could not have intended 16 that the AWP prong of this regulation would have 17 yielded a spread of zero because Medicare 18 understood that AWP exceeded estimated acquisition 19 cost in many cases by a considerable amount; 20 correct? 21 MR. SOBOL: Objection to form. 22 A. I was not asked to do an analysis of</p>

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<p style="text-align: right;">886</p> <p>1 those issues. The analysis I was asked to do, 2 which I think I have laid out pretty clearly, is 3 that to identify what -- what the expected 4 relationship between AWP and the various 5 transaction costs, most importantly ASP was, to 6 set a bound for that, and having done so, go back 7 to the Medicare statute and see if there are 8 implications therefrom for those drugs where 9 liability was -- that liability threshold was 10 exceeded, what the implications were under the 11 statute for payment, and that's what I have done. 12 I haven't been asked -- I haven't been asked to 13 analyze what -- how Medicare thought about that or 14 anything else. 15 Q. Well, let me ask you this. If the 16 regulation had simply said payment for a drug will 17 be at AWP, would you have construed that to mean 18 zero by statute? 19 MR. SOBOL: Objection. 20 A. Zero by statute? That the spread would 21 be zero? I don't -- I don't understand. What is 22 zero? Are we talking about --</p>	<p style="text-align: right;">888</p> <p>1 relative to what the implications were for the 2 spread, and there is, for the single-source drugs, 3 you are seeing '91 to 2003 that spread of zero. 4 I think it is a little clearer to go 5 from -- to make this a little more 6 straightforward, to go right to paragraph 64, the 7 next one, where that zero is translated into what 8 the real calculation is, because I think that will 9 make it clearer what we're talking about here. 10 When the spread is zero, it means that 11 anything where the AWP exceeds the ASP is a 12 measure of damages, and then for '98 through 2003, 13 it is 95 percent of AWP. So this will allow us to 14 talk about what I mean by a zero spread and what 15 the implications are for the calculations of 16 damages, because in 64 is the way it is done. 17 So if you could rephrase -- I mean all 18 of the things we have been saying was the 19 estimated acquisition cost is the ASP. That is 20 their AWP. 21 You had a hypothetical now about suppose 22 they charged AWP or -- if you could rephrase that.</p>
<p style="text-align: right;">887</p> <p>1 Q. Well, that is your language. 2 A. Well, are we talking about -- but we are 3 talking about -- you are mixing the measure of a 4 spread. If -- if we want to use my language, 5 let's refer to the paragraph in which we're using 6 it, because there is some complexity of going 7 between the spreads, and a zero spread, and then 8 the damage calculation that is a difference 9 between an AWP and an ASP, and I think -- let me 10 just draw your attention to it. It may make it 11 easier. 12 (Pause.) 13 (The witness viewing Exhibit 14 Hartman 023.) 15 A. That is in paragraph 63, this is where 16 there is this notion of the zero spread. I will 17 let you get there. 18 Q. I'm there. 19 A. Okay. Here is the description, because 20 much of the language was related to measured 21 spreads and a yardstick spread for liability, I 22 first put in the damage language and calculations</p>	<p style="text-align: right;">889</p> <p>1 Q. Yes. My question to you, Dr. Hartman, 2 was whether if the regulation had simply said 3 reimbursement will be at AWP, you would have 4 concluded that the proper reimbursement rate was a 5 zero spread by statute. 6 A. No. 7 Q. Okay. 8 MR. EDWARDS: Now I want to mark as 9 Exhibit Hartman 039 a copy of a letter from Frank 10 Camozzi, chief of the technical issue section of 11 Medicare, to S. Stewart dated November 4, 1994, 12 the Bates stamps are HHC 015-1693 to 94. 13 (Two-page letter dated November 4, 14 1994, to Ms. S. Stewart from Mr. Camozzi marked 15 Exhibit Hartman 039 for identification.) 16 (Handing Exhibit Hartman 039 to the 17 witness.) 18 BY MR. EDWARDS: 19 Q. Have you ever seen this document before? 20 A. No. DMSO? Wow. 21 Q. Are you aware that the government has 22 made a significant production to the defendants in</p>

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<p style="text-align: right;">890</p> <p>1 this case of documents relating to this issue?</p> <p>2 A. Which issue are we talking about here?</p> <p>3 Do you mean the issue of --</p> <p>4 Q. The issue of reimbursement under</p> <p>5 Medicare.</p> <p>6 A. I've had my staff review and told them</p> <p>7 to review a variety of documents that fit within</p> <p>8 certain guidelines. I don't remember them putting</p> <p>9 -- bringing this to my attention or some of the</p> <p>10 other -- I mean I don't know how substantial the</p> <p>11 correspondence is, but I have not seen this.</p> <p>12 Q. In the third paragraph of this letter,</p> <p>13 Mr. Camozzi says, quote, "However, the Healthcare</p> <p>14 Financing Administration, HCFA, has not yet</p> <p>15 implemented the estimated acquisition cost portion</p> <p>16 of this regulation or provided carriers with</p> <p>17 specific instructions on how to execute this</p> <p>18 segment of the drug payment policy."</p> <p>19 Is that consistent with your</p> <p>20 understanding?</p> <p>21 A. As I say, my understanding was that the</p> <p>22 surveys had not been done and the information had</p>	<p style="text-align: right;">892</p> <p>1 understood, and what that meant in terms of legal</p> <p>2 implications, I do not know.</p> <p>3 Q. So you didn't know that the estimated</p> <p>4 acquisition cost portion of the regulation had not</p> <p>5 been implemented?</p> <p>6 A. I, you know, judging from this, I don't</p> <p>7 know one way or the other. I don't know what that</p> <p>8 means, "has not been implemented."</p> <p>9 Q. Well, would it be fair to say that "has</p> <p>10 not been implemented" means has not been</p> <p>11 implemented?</p> <p>12 A. Well, it would be fair to say the</p> <p>13 following. That since no one had done any surveys</p> <p>14 that I know of, no one knew what an estimated</p> <p>15 acquisition cost was, so it -- whether -- so there</p> <p>16 -- so that it would be impossible to implement</p> <p>17 this particular section of CFR from '92 to '97 in</p> <p>18 my footnote.</p> <p>19 Q. Well, you said you base your</p> <p>20 interpretation of the regulation on your</p> <p>21 understanding of the English language. Is it</p> <p>22 consistent with your understanding of the English</p>
<p style="text-align: right;">891</p> <p>1 not been gathered, and if this is -- you know, if</p> <p>2 this is an offshoot of that, you know, I didn't -</p> <p>3 - I didn't know this -- this followed.</p> <p>4 Q. Well, as of November 4, 1994, at least,</p> <p>5 the EAC prong of the regulation on which you rely</p> <p>6 had not been implemented; correct?</p> <p>7 A. I am not sufficiently schooled in the</p> <p>8 administrative law or whatever to make -- to make</p> <p>9 any judgment from this letter one way or the</p> <p>10 other. I mean that's something for a lawyer to</p> <p>11 conclude.</p> <p>12 Q. Do you know whether it had been</p> <p>13 implemented as of 1995 or 1996?</p> <p>14 A. Are we talking about have the surveys</p> <p>15 been implemented, or are you talking about now</p> <p>16 this acquisition portion of the regulation?</p> <p>17 Q. I am talking about the estimated</p> <p>18 acquisition cost portion of the regulation.</p> <p>19 A. As I say, I've -- my understanding of</p> <p>20 the regulations are as put forward in the footnote</p> <p>21 we've been talking about. I had understood that</p> <p>22 the surveys had not been done, and that's all I</p>	<p style="text-align: right;">893</p> <p>1 language that the words "has not been implemented"</p> <p>2 in this document means exactly what they say, has</p> <p>3 not been implemented?</p> <p>4 A. Well, I see -- I see this in re: HCPCS</p> <p>5 code J 1212, injection of DMSO, and so I don't</p> <p>6 know whether this is -- I don't -- this does not</p> <p>7 seem to me to be a broad-based policy letter.</p> <p>8 Maybe it is. I just -- I don't know. I can't tell</p> <p>9 from this.</p> <p>10 I don't -- if this were in re, you know,</p> <p>11 the implications of estimating -- of estimated</p> <p>12 acquisition cost portion, then I -- then I would</p> <p>13 see a broader application. I don't know. It does</p> <p>14 say that. But how broad -- broadly that went</p> <p>15 through, all drug reimbursement -- I know there</p> <p>16 were -- estimated acquisition costs were out</p> <p>17 there. They could -- I mean there were</p> <p>18 acquisition costs. One could estimate them. They</p> <p>19 weren't -- Medicare wasn't doing it. So it be</p> <p>20 would very hard to implement this calculation that</p> <p>21 I have gone ahead and implemented.</p> <p>22 Q. I take it you have never talked to</p>

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1 anybody who worked at HCFA during this time period
2 in order to determine whether your interpretation
3 of the regulation is correct?

4 A. I have never talked to anyone at HCFA
5 about whether because the surveys had not been
6 done that essentially this phrasing is such that -
7 - that they -- that there was no estimated
8 acquisition cost. I would have to say that from
9 '98 through 2003 they went to the lower of the
10 actual bill -- actual charge, which by its nature
11 is an estimated acquisition cost, and there is
12 discussion in footnote 14 from CMS of what that
13 means, and so there was -- there was -- you know,
14 whether this, you know, average worked and how far
15 it went, there is still clearly some reliance on
16 acquisition costs, and as it was stated in the '98
17 through 2003 regulation.

18 So I haven't done -- I have taken -- I
19 have taken the CFR as it reads and assumed that
20 that was the guiding -- that was what was guiding
21 reimbursement.

22 Q. Well, you just stated that the law was

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1 changed in 1997 or 1998 to indicate that
2 reimbursement would be based on the lower of the
3 billed charge or 95 percent of AWP?

4 A. The actual charge or 95 percent of the
5 national AWP.

6 Q. And it is your testimony that the words
7 "actual charge" in that context refer to the
8 amount that the physician paid for the drug?

9 A. Well, it is not just my testimony. It
10 is the testimony of CMS. In footnote 14 I cite
11 Thomas Scully talking about how these types of
12 drugs would be reimbursed, "and by law, we
13 generally pay for these drugs based on the actual
14 charge or 95 percent of the AWP, whichever is
15 lower," which says to me it is -- the bill charges
16 the acquisition, whichever is lower, and Mr. Young
17 clarifies that further in the same footnote where
18 he says in his paragraph 170, "From 1992 to date,
19 moreover, reimbursement under Medicare Part B has
20 generally been made at the lower of the billed
21 charge amount or AWP through '97 or 95 percent of
22 AWP after '97. The carriers may reimburse at less

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1 than the AWP base rates where, for instance, the
2 physician's bill charges are less."

3 That is acquisition cost.

4 Now I mean maybe Mr. Young is wrong, and
5 maybe Mr. Scully is wrong, but I have -- this
6 entire notion of acquisition, bill charged, it has
7 been in that vein that I have seen it throughout
8 the Medicare regulations.

9 Q. How do you know that the phrase "billed
10 charge" does not refer to the charge that the
11 physician puts on the Medicare claim as opposed to
12 the price that the physician pays for the drug?

13 A. It is my reading of these particular
14 citations and other materials which I can't -- I
15 can't recall right now. I can try and look --
16 look at what those cites are.

17 Q. Are you prepared to stake your
18 reputation on that reading?

19 MR. SOBOL: Objection.

20 A. Stake my reputation?

21 Q. Your reading could be wrong; correct?

22 A. My reputation as a reader or as what? I

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1 am not -- I am not an expert in -- we know I am
2 not an expert in Medicare regulations, and I am
3 reading what some of your own experts have said,
4 and I'm reading what some of the CMS
5 representatives and -- let's see what it -- what
6 it is -- the CMS administrator has said, and I am
7 interpreting it in that way, and that's as --

8 Q. Well, what Mr. Scully and Mr. Young said
9 is not inconsistent with the interpretation that
10 "actual charge" refers to the charge that the
11 physician puts on the Medicare claim form as
12 opposed to the price that the physician pays for
13 the drug; correct?

14 A. It is my understanding that they were to
15 be one and the same.

16 MR. EDWARDS: What I am going to do is
17 mark as Deposition Exhibit Hartman 040 a copy of
18 42 CFR 405.517 revised as of October 1, 1999.
19 (42 CFR 405.517 marked Exhibit
20 Hartman 040 for identification.)

21 MR KAUFMAN: Excuse me, Steve. Is this
22 number Exhibit Hartman 040?

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<p style="text-align: right;">898</p> <p>1 THE REPORTER: Exhibit Hartman 040. 2 (Handing Exhibit Hartman 040 to the 3 witness.) 4 BY MR. EDWARDS: 5 Q. Have you seen Exhibit Hartman 040 6 before? 7 A. I think I have. 8 Q. You have actually looked at the 9 regulation? 10 A. Oh, yes. I have had copies of each of 11 these, the subsections. The boxed -- the boxed 12 portions, I have had my staff pull out the 13 specific wording that was applicable here, and at 14 times, I have looked at it more broadly, but. 15 Q. So let me direct your attention to 16 subsection B, which says "Methodology. Payment for 17 a drug or biological described in paragraph A of 18 this section is based on the lower of the actual 19 charge on the Medicare claim for benefits or 95 20 percent of the national average wholesale price of 21 the drug or biological." 22 Doesn't this demonstrate conclusively</p>	<p style="text-align: right;">900</p> <p>1 pointing to appears verbatim in my footnote 13 2 under the guiding regulations for 1998 through 3 2003, so it is -- it is clear that I have read 4 this. It is clear that I have taken this into 5 account. 6 I have looked at the, as I said, said 7 under footnote 14, additional testimony, and when 8 I see here that the defendants' expert Steven 9 Young has said that reimbursement under Medicare 10 Part B is generally made at the lower of the 11 billed charged amount, and that's what I am taking 12 to be the amount charged on the Medicare claim -- 13 Q. But billed by whom? 14 A. I am taking the billed charge on the 15 part of the physician to be the same as the billed 16 amount to the physician. 17 Q. Where does it say that? Where does it 18 say that the charge that the physician puts on the 19 Medicare claim form has to be the same as the 20 price that the physician paid to the manufacturer? 21 A. I have told you that this is based on my 22 broad -- broader reading of the documents in this</p>
<p style="text-align: right;">899</p> <p>1 that your interpretation of the statute is wrong? 2 MR. SOBOL: Objection. 3 A. No. 4 MR. SOBOL: Before we go ahead, I know 5 it is five o'clock. 6 Q. Doesn't this demonstrate conclusively 7 that the statute -- 8 MR. SOBOL: Hold on a second. Relax. 9 MR. EDWARDS: Excuse me? 10 MR. SOBOL: I know it is five o'clock. 11 Do you want to finish your questions on this 12 document? 13 MR. EDWARDS: Yes. 14 MR. SOBOL: Okay. 15 BY MR. EDWARDS: 16 Q. Doesn't this demonstrate conclusively 17 that the words "actual charge" was -- were 18 designed to reflect the charge that the physician 19 put on the claim for benefits as opposed to the 20 amount that the physician was charged by the 21 manufacturer? 22 A. The particular sentence that you are</p>	<p style="text-align: right;">901</p> <p>1 matter, conversions with our affiliates at the 2 Harvard School of Public Health regarding Medicare 3 types of reimbursement, and it is based on that 4 broad set of evidence. 5 Q. Did you read the legislative history of 6 the Balanced Budget Act in 1997 which gave rise to 7 this change in the Medicare reimbursement formula? 8 MR. SOBOL: Objection to the form. 9 A. It is my recollection I have read 10 portions of that, but I -- I -- I -- it's -- I'm 11 not certain. 12 Q. And are you aware of the fact that the 13 Clinton administration proposed to Congress that 14 reimbursement be based on the estimated 15 acquisition cost of the physician and Congress 16 rejected that? 17 MR. SOBOL: Objection. 18 A. I -- I am aware that there was -- there 19 was much disagreement among various stakeholders 20 in how reimbursement rates should be paid and 21 calculated, and we have been talking about it all 22 day.</p>

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1 Q. Are you aware of the fact that Congress
2 rejected EAC as a basis for reimbursement in the
3 Balanced Budget Act of 1997?
4 MR. SOBOL: Objection to the form. You
5 may answer.
6 A. I think I have cited -- I know that Mr.
7 Young has talked about that, and -- and so I -- I
8 am generally aware of -- that there has been that
9 debate and certain proposals have been rejected.
10 Q. And are you aware that that specific
11 proposal was rejected?
12 MR. SOBOL: Objection to the form.
13 A. I'm not aware of the specificity of
14 individual proposals being either rejected or
15 accepted.
16 MR. EDWARDS: At this point, I would
17 move on to some additional documents, Tom.
18 MR. SOBOL: Let's suspend for the day
19 and reconvene tomorrow morning at 9:30, which is
20 early for Mr. Hartman. That's why we're not
21 starting earlier.
22 MR. EDWARDS: He will be here at eight

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1 o'clock.
2 THE WITNESS: That is why I cannot take
3 breaks.
4 MR. KAUFMAN: He is superman. He doesn't
5 take breaks.
6 MR. SOBOL: Because he is late to work
7 every day.
8 THE VIDEOGRAPHER: The time is 5:08. The
9 deposition is suspended. This is the end of
10 cassette 4. We are off the record.
11 (Whereupon, at 5:08 p.m., the
12 deposition was adjourned.)
13
14
15
16 RAYMOND S. HARTMAN, Ph.D.
17 Subscribed and sworn to and before me
18 this _____ day of _____, 20____.
19
20
21
22 Notary Public

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1 CERTIFICATE
2 Commonwealth of Massachusetts
3 Plymouth, ss.
4 I, Judith McGovern Williams, a Registered
5 Professional Reporter and Notary Public in and for the
6 Commonwealth of Massachusetts, do hereby certify:
7 That RAYMOND S. HARTMAN, PH.D., the witness
8 whose deposition is hereinbefore set forth, was duly
9 sworn by me and that such deposition is a true record
10 of the testimony given by the said witness.
11 IN WITNESS WHEREOF, I have hereunto set my
12 hand this _____ day of _____, 2006.
13
14
15
16 Judith McGovern Williams
17 Registered Professional Reporter
18 Certified Realtime Reporter
19 Certified LiveNote Reporter
20 Certified Shorthand Reporter No. 130993
21 My Commission expires:
22 April 2, 2010

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<p style="text-align: right;">866</p> <p>1 market power? Is that what you're saying?</p> <p>2 MR. SOBOL: Objection.</p> <p>3 A. No. I just -- I made a comment about</p> <p>4 what generated market power on the part of</p> <p>5 physicians, and the --</p> <p>6 Q. Well, why are payers willing to let</p> <p>7 physicians earn up to 30 percent on drugs in your</p> <p>8 view?</p> <p>9 A. In my view, it reflects what Mr. -- what</p> <p>10 Mr. Young had stated: That in prior to 1992,</p> <p>11 going into 1992, Medicare essentially reimbursed</p> <p>12 on a cost basis, and the cost was assumed to be</p> <p>13 more or less AWP, and that -- and as -- as the</p> <p>14 transition went into more focus on reimbursement</p> <p>15 under Medicare, there was a realization that</p> <p>16 reimbursement at AWP or some percent -- and then</p> <p>17 the percentage off of AWP and the private third-</p> <p>18 party payers, that allowed the doctors to earn</p> <p>19 what was the retail margin, more or less.</p> <p>20 So there is a small margin that the</p> <p>21 doctors were earning as part of their</p> <p>22 administering the drugs, and I don't think that</p>	<p style="text-align: right;">868</p> <p>1 look at the Dyckman figure 13 -- oh, no, -- oh,</p> <p>2 yes, that is right.</p> <p>3 So if I am on average, this average is</p> <p>4 about 97 percent of AWP, and so for the aggregate</p> <p>5 measure of what the payers are willing to -- have</p> <p>6 been reimbursing or the profits that are earned on</p> <p>7 aggregate by the providers, at some aggregate</p> <p>8 measure, it is 97 percent -- 95 -- 97.5 percent</p> <p>9 AWP less ASP, over ASP, so it is a little less</p> <p>10 than 30 percent.</p> <p>11 Q. Well, let's take a contract where the</p> <p>12 reimbursement rate is AWP.</p> <p>13 A. That's fine. Then we are at 30 percent.</p> <p>14 Q. In that situation, you would agree with</p> <p>15 me that the provider is willing to -- I am sorry -</p> <p>16 - that the payer is willing to enable the provider</p> <p>17 to earn a profit of 30 percent over the</p> <p>18 acquisition cost of the drug; correct?</p> <p>19 MR. SOBOL: Objection.</p> <p>20 A. In that world, the provider is allowed</p> <p>21 to drive the speed limit.</p> <p>22 Q. Right. And the payer is agreeing with</p>
<p style="text-align: right;">867</p> <p>1 was a -- they weren't thinking about market power</p> <p>2 at that point or -- whatever they -- the</p> <p>3 realization of the market power was on the part of</p> <p>4 the manufacturers in terms of increasing the</p> <p>5 spread.</p> <p>6 Q. But that margin is 30 percent; right?</p> <p>7 A. With the --</p> <p>8 MR. SOBOL: Objection.</p> <p>9 A. No.</p> <p>10 Q. In other words, in your but-for world,</p> <p>11 assuming a payer understood what ASP was and sat</p> <p>12 down with a provider and negotiated a contract,</p> <p>13 that payer should be willing to reimburse that</p> <p>14 provider at a rate that is 30 percent above the</p> <p>15 ASP; correct?</p> <p>16 MR. SOBOL: Objection.</p> <p>17 A. When we look at the Medpac survey, we</p> <p>18 find that different payers have themselves</p> <p>19 different amounts of clout in the negotiations,</p> <p>20 such that they are willing to -- they agree to</p> <p>21 reimburse AWP less 15 percent, 85 percent of AWP,</p> <p>22 and some are up to AWP plus 10 percent. If we</p>	<p style="text-align: right;">869</p> <p>1 the provider, basically it is okay with me if you</p> <p>2 earn 30 percent on these drugs; that's why I am</p> <p>3 setting the AWP -- I am sorry -- that is why I am</p> <p>4 setting the reimbursement rate at AWP; correct?</p> <p>5 A. The -- that is assuming the provider</p> <p>6 knows -- the payer knows the ASP. The payer until</p> <p>7 2005 did not.</p> <p>8 Q. But I want you to --</p> <p>9 A. But, you know, there is some -- the</p> <p>10 providers up until that point saw some of these</p> <p>11 anecdotal information, but that would have said to</p> <p>12 me prior to 2005 that the provider -- the payer</p> <p>13 thought, well, the guy is earning the retail</p> <p>14 margin plus some, so, you know, could be making 10</p> <p>15 percent, 15 percent above ASP, 5 percent.</p> <p>16 Q. Well, assume with me that the payer knew</p> <p>17 what the ASP was --</p> <p>18 A. Okay.</p> <p>19 Q. -- and the payer agreed to reimburse the</p> <p>20 provider at AWP. In that scenario, the payer</p> <p>21 would be agreeing that the provider could earn a</p> <p>22 margin of 30 percent; correct?</p>

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1 A. In that -- in that example, the payer
2 agrees to the upper bound of the expectations that
3 I have found in the data that had been used for my
4 -- for the liability yardstick in my December
5 declaration.

6 Q. And that 30 percent would essentially
7 reflect the providers' market power in that
8 particular negotiation; correct?

9 A. No. I mean they are also negotiating
10 the fees, so that there are other things being
11 negotiated. Money being paid to the provider is
12 not just the amount on the drugs. There is fees,
13 and there is -- there is other things being
14 negotiated.

15 Q. So you can't really analyze the impact
16 of the spread in a situation like this without
17 looking at all of the other aspects of the
18 contractual relationship between the payer and the
19 provider? Is that what you're saying?

20 A. No.

21 Q. What is your definition of market power?

22 A. Market power can -- the traditional

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1 textbook definition of market power in thinking
2 about a monopolist is that, or a small group of
3 producers, is that there is essentially enough
4 control of production in that market that there is
5 the power to raise price above cost, and that's a
6 textbook definition of --

7 Q. And in the particular --

8 A. -- one of --

9 Q. -- example I just recited where the
10 provider has been reimbursed at AWP, that provider
11 has sufficient market power to raise the price to
12 30 percent above cost; correct?

13 MR. SOBOL: Objection to the form.

14 A. We've -- the -- we have already
15 discussed -- I mean right now we're talking about
16 a variety of different notions of market power. I
17 mean there is -- I have given you the textbook
18 example, but another notion of having power to
19 influence the market or market power is to move
20 market share, and that is something that is --
21 that is retained and that reflects the physician's
22 position and the providers' position in the

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1 provider -- in the world of providers.

2 So that, that type of market power
3 relative to the -- his clients, the doctors'
4 clients, the patients, and what they are going to
5 end up paying for, that -- that is a market power
6 that -- it -- we're -- is a little bit off what
7 you're trying to get at here. You are talking
8 about the payers trying to pay them something or -
9 - I'm not talking -- the market power I am talking
10 about is not in negotiating with the payer right
11 now. I am talking about the ability to move
12 patients from one drug to another, and that power,
13 and that right now is not -- that's - - we're not
14 -- they're not -- that's not being -- I am not
15 sitting down as a provider and negotiating with a
16 payer just based on that notion.

17 Q. Are you saying that providers have no
18 market power in their negotiations with payers?

19 A. I would say that there is some providers
20 that have -- I would say that there is variation
21 in that market power.

22 Q. In the situation where the provider is

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1 able to earn a profit of 30 percent over ASP, how
2 much of that 30 percent is attributable to the
3 providers' market power?

4 A. The revealed negotiations of the
5 implications of market power and the ability in
6 the negotiations to effectuate reimbursement and,
7 therefore, demonstrate market power is shown in
8 Exhibit 13 of the Dyckman report where the
9 percentage off of AWP ranges from 85 to 115. So
10 this is merely one measure of what the ability is
11 of a provider to take advantage of whether it is a
12 large oncology group or just a single
13 practitioner. The service fees and other things
14 are also part of that. So you are -- that
15 question can't be answered only looking at drug
16 costs.

17 Q. So but you are saying that some part of
18 that 30 percent would be attributable to the
19 provider's market power? You just haven't figured
20 out what it is yet; correct?

21 MR. SOBOL: Objection.

22 A. It is -- the question is so -- I don't -

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<p style="text-align: right;">874</p> <p>1 - I don't understand what you mean by parsing that 2 and attributing part of it. I -- I -- I guess I 3 don't really understand what you're getting at. 4 Q. Is any part of it attributable to the 5 provider's market power? 6 A. Well, one can certainly say that in a 7 negotiation where there is some understanding of 8 what acquisition costs are and that is -- there is 9 asymmetric information. Up to 2005, apparently 10 only the provider knew what the ASP was, except 11 for anecdotal information in Barron's and reports 12 here and there, but as providers sat down and 13 negotiated with payers, they were able to extract 14 -- they knew what their ASP was for all their 15 drugs, and they were able -- some were able to 16 say, look, I want to be reimbursed AWP plus 15 -- 17 plus 15 percent. Well, they were in a stronger 18 position to negotiate in that bilateral 19 negotiation, and they revealed power. 20 Now that is not really the classic 21 definition of market power, and I don't know 22 really what you're getting at with market power</p>	<p style="text-align: right;">876</p> <p>1 analysis of that. 2 MR. EDWARDS: Time for a short break? 3 MR. SOBOL: Okay. 4 THE VIDEOGRAPHER: The time is 4:14. 5 This is the end of cassette number 3. We are off 6 the record. 7 (Recess taken at 4:14 p.m.) 8 (Recess ended at 4:28 p.m.) 9 THE VIDEOGRAPHER: The time is 4:28 p.m. 10 This is the beginning of cassette number 4 in the 11 deposition of Mr. Raymond Hartman. We are on the ~ 12 record. 13 BY MR. EDWARDS: 14 Q. Dr. Hartman, I want to turn to that 15 portion of your report that deals with the damage 16 yardstick for Medicare, and I guess in your 17 supplemental report, it is the yardstick for 18 liability and damages, and that is the yardstick 19 that you have characterized as, I think, zero by 20 statute in your previous testimony; is that 21 correct? 22 A. I've -- I've used the shorthand that the</p>
<p style="text-align: right;">875</p> <p>1 and percentages of this related to that. We are 2 talking about the ability in a negotiation to come 3 up with some -- some relationship of what your 4 reimbursement is going to be, period, and that is 5 based on -- historically based on the providers 6 knew what their ASPs were; Medicare and the payers 7 did not. They came to understand what they were. 8 But this distribution here indicates the 9 ability of payers -- of providers to say, "I want 10 a higher -- no matter what my ASP is, I want more 11 money to be reimbursed to me from you," and they 12 get it, so that is power. 13 (Pointing to Exhibit Hartman 020.) 14 A. That's an ability to take advantage of 15 the position, your market position, and increase 16 your price. 17 Q. Have you considered whether some payers 18 don't care about the cost of individual drugs to 19 the provider? All they care about is the bottom- 20 line profitability of the provider? 21 A. I would -- I haven't -- you know, I 22 could speculate, but I haven't done any detailed</p>	<p style="text-align: right;">877</p> <p>1 spread would be zero in that case. That 2 essentially that the re -- yes. That's -- yes. 3 Q. And the statute is what statute? 4 A. Well, it is an unfolding set of statutes 5 and revisions that are laid out in footnote 13, 6 which has the sources within the CFR regulations 7 of what the reimbursement under Medicare would be, 8 and for single-source and multi-source drugs, so 9 it essentially is the basis for wherever I cite a 10 spread or a calculation for damages, it is based 11 on the Medicare statutes as they are summarized in 12 footnote 13. 13 Q. For the period 1992 through 1997, are 14 you talking about a statute or a regulation? 15 A. I'm -- it is my understanding it is a 16 regulation. I -- not being a lawyer, I kind of 17 think of them as the same, and actually, I almost 18 thought -- I thought Judge Saras referred to them 19 as statutory enablement, too. 20 Q. Are you familiar with the regulation? 21 A. You know, I have skimmed parts of it. I 22 am familiar with these sections of it. I mean</p>

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1 there is a lot of paper involved with every
2 revision.
3 MR EDWARDS: What I want to do is mark
4 as Exhibit Hartman 038 a copy of an excerpt of the
5 regulation, which is 45 CFR -- no -- it is 42 CFR.
6 I believe it is 405.
7 THE WITNESS: .517 maybe.
8 (Excerpt from Federal Register
9 marked Exhibit Hartman 038 for identification.)
10 BY MR. EDWARDS:
11 Q. Which portion of the regulation do you
12 rely on? And let me just say that we have
13 provided a copy of the actual regulation as it
14 appears in the Federal Register, but it is --
15 A. Blurry.
16 Q. -- hard to read, and there is a typed-
17 up version attached to it.
18 A. I thought you just gave me -- I thought
19 it was like the dribble glass. This is the
20 dribble exhibit that I can't really read. I mean I
21 am having trouble.
22 Q. Why don't you look at the last page of

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1 this document, Exhibit Hartman 038.
2 (Witness complying.)
3 A. Okay. And?
4 Q. There is a reference to Section 405.517.
5 Is that the regulation that you rely on?
6 A. The last page of all of the typed pages
7 or -- oh, I see here. Okay. 405.517?
8 (Pause.)
9 (The witness viewing Exhibit
10 Hartman 038.)
11 A. That is correct. That is what is
12 summarized in footnote 12 for reimbursement
13 covering the period '92 through 1997.
14 Q. Now you admitted at your last deposition
15 that you are not an expert on Medicare regulations
16 and you don't have a law degree. Has that
17 changed?
18 A. No.
19 Q. Are you expressing an expert opinion
20 that it is zero by statute, or are you simply
21 assuming that that will be proven by other means,
22 and you are just running the numbers, assuming

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1 that proposition is established?
2 A. I would frame it -- I am -- I am --
3 maybe the answer is yes to that, but let me just
4 see, make sure.
5 The statute is what it is, and it says
6 how reimbursement should be paid under Medicare
7 claims, and given that, that's my understanding of
8 what the regulations are and how reimbursement
9 should have been paid by Medicare, and that just -
10 - that exists. I -- I then go and do analyses of
11 thresholds of liability to see whether drugs are
12 applicable to evaluating what the implications of
13 this alternative reimbursement strategy --
14 reimbursement regulation is if the reimbursement
15 was not at the acquisition cost.
16 Q. So you are offering an opinion on the
17 proper interpretation of this regulation?
18 A. I am offering an interpretation on --
19 that is nothing more than my reading of what --
20 what you have in a box there about what -- what
21 the reimbursement rate should be. That it is going
22 to be, as I have stated in that footnote, payment

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1 for a drug is based on the lower of the estimated
2 acquisition cost or the national average wholesale
3 price of the drug. That -- and that's what it
4 says here. And then for multi- source drugs, the
5 payment is based on the lower of the estimated
6 acquisition cost or the wholesale price for
7 purposes -- for that period of time. It is
8 defined as median price for all sources of the
9 generic form of the drug, so.
10 Q. What is it that qualifies you to offer
11 that opinion?
12 A. My ability to read.
13 Q. Nothing more?
14 A. That's right.
15 Q. So anybody could offer this opinion?
16 A. If -- I am assuming this is how
17 reimbursement was to be made, and because I am
18 reading it here in the regulations, and that's --
19 that's as far as my opinion goes.
20 Q. This opinion doesn't depend on your
21 expertise as an economist; correct?
22 A. That's correct.

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<p style="text-align: right;">882</p> <p>1 Q. You did not take any courses on 2 statutory interpretation in graduate school; 3 correct? 4 A. No. 5 Q. Now this regulation actually says that 6 estimated acquisition cost and average wholesale 7 price are two different things, doesn't it? 8 A. I'm sorry. Could you say that again? I 9 was -- it -- it? 10 Q. This regulation says, "Payment for a 11 drug described in paragraph A of this section is 12 based on the lower of the estimated acquisition 13 cost or" -- and it uses the word "or" -- "the 14 national average wholesale price of the drug." 15 Correct? 16 A. That's correct. 17 Q. And the use of "or" in that context 18 suggests that estimated acquisition cost and AWP 19 are two different things; correct? 20 A. They -- they could -- they could be 21 equal to the same thing, but it is not -- but it 22 doesn't -- it says "or," so it is the lesser of.</p>	<p style="text-align: right;">884</p> <p>1 A. Well, it's -- the -- the reimbursement 2 rate is not zero. The spread, the measured 3 spread, would be zero. The -- essentially what 4 the -- what this is saying is, "Look, if you are 5 going to reimburse, you are going to reimburse at 6 AWP or the estimated acquisition cost," and the 7 estimated acquisition cost was out there. It is 8 just the surveys weren't done to inform Medicare 9 what it was. 10 Q. But your opinion that it is zero by 11 statute is based on the estimated acquisition cost 12 part of this regulation; correct? 13 A. My calculation of damages, if a -- in my 14 December report, if a drug exceeds a threshold of 15 liability, of the 30 percent, then there is a 16 calculation of what are the implications of the 17 deviation of a reimbursement being at AWP when by 18 statute it should have been by -- at the estimated 19 acquisition cost. 20 Q. You are assuming that estimated 21 acquisition cost, if it had been implemented, 22 would have yielded a spread of zero; correct?</p>
<p style="text-align: right;">883</p> <p>1 Q. The lesser of, so it is two different 2 things; correct? 3 A. One or the other. Yes. Two different 4 measures. 5 Q. And as far as you know, Medicare 6 understood that estimated acquisition cost and AWP 7 were two different things; correct? 8 A. That's my understanding. 9 Q. The regulation goes on to say that "The 10 estimated acquisition cost is determined based on 11 surveys of the actual invoice prices paid for the 12 drug." 13 Do you know whether those surveys were 14 ever conducted? 15 A. It's my understanding they were not. 16 Q. So the estimated acquisition cost part 17 of this regulation was never implemented; correct? 18 A. Those surveys were not -- were not done. 19 Q. So you are basing your opinion that the 20 proper reimbursement rate under Medicare is zero 21 by statute on a provision of a regulation that was 22 never implemented?</p>	<p style="text-align: right;">885</p> <p>1 A. The -- 2 Q. In other words, EAC would have equalled 3 ASP as defined in your December 15th report? 4 A. EAC would be equal to the estimated -- 5 the -- it is also referred to as the average 6 acquisition cost in some -- in some of the 7 descriptions of this. 8 But the average acquisition cost is the 9 average sales price to the set of providers that 10 we're talking about, and to the extent that the 11 AWP exceeds that average sale price, under this 12 payment regulation I calculate the extent of that 13 spread as a measure to which the reimbursement was 14 greater than the estimated acquisition cost. 15 Q. Well, Medicare could not have intended 16 that the AWP prong of this regulation would have 17 yielded a spread of zero because Medicare 18 understood that AWP exceeded estimated acquisition 19 cost in many cases by a considerable amount; 20 correct? 21 MR. SOBOL: Objection to form. 22 A. I was not asked to do an analysis of</p>

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<p style="text-align: right;">886</p> <p>1 those issues. The analysis I was asked to do, 2 which I think I have laid out pretty clearly, is 3 that to identify what -- what the expected 4 relationship between AWP and the various 5 transaction costs, most importantly ASP was, to 6 set a bound for that, and having done so, go back 7 to the Medicare statute and see if there are 8 implications therefrom for those drugs where 9 liability was -- that liability threshold was 10 exceeded, what the implications were under the 11 statute for payment, and that's what I have done. 12 I haven't been asked -- I haven't been asked to 13 analyze what -- how Medicare thought about that or 14 anything else. 15 Q. Well, let me ask you this. If the 16 regulation had simply said payment for a drug will 17 be at AWP, would you have construed that to mean 18 zero by statute? 19 MR. SOBOL: Objection. 20 A. Zero by statute? That the spread would 21 be zero? I don't -- I don't understand. What is 22 zero? Are we talking about --</p>	<p style="text-align: right;">888</p> <p>1 relative to what the implications were for the 2 spread, and there is, for the single-source drugs, 3 you are seeing '91 to 2003 that spread of zero. 4 I think it is a little clearer to go 5 from -- to make this a little more 6 straightforward, to go right to paragraph 64, the 7 next one, where that zero is translated into what 8 the real calculation is, because I think that will 9 make it clearer what we're talking about here. 10 When the spread is zero, it means that 11 anything where the AWP exceeds the ASP is a 12 measure of damages, and then for '98 through 2003, 13 it is 95 percent of AWP. So this will allow us to 14 talk about what I mean by a zero spread and what 15 the implications are for the calculations of 16 damages, because in 64 is the way it is done. 17 So if you could rephrase -- I mean all 18 of the things we have been saying was the 19 estimated acquisition cost is the ASP. That is 20 their AWP. 21 You had a hypothetical now about suppose 22 they charged AWP or -- if you could rephrase that.</p>
<p style="text-align: right;">887</p> <p>1 Q. Well, that is your language. 2 A. Well, are we talking about -- but we are 3 talking about -- you are mixing the measure of a 4 spread. If -- if we want to use my language, 5 let's refer to the paragraph in which we're using 6 it, because there is some complexity of going 7 between the spreads, and a zero spread, and then 8 the damage calculation that is a difference 9 between an AWP and an ASP, and I think -- let me 10 just draw your attention to it. It may make it 11 easier. 12 (Pause.) 13 (The witness viewing Exhibit 14 Hartman 023.) 15 A. That is in paragraph 63, this is where 16 there is this notion of the zero spread. I will 17 let you get there. 18 Q. I'm there. 19 A. Okay. Here is the description, because 20 much of the language was related to measured 21 spreads and a yardstick spread for liability, I 22 first put in the damage language and calculations</p>	<p style="text-align: right;">889</p> <p>1 Q. Yes. My question to you, Dr. Hartman, 2 was whether if the regulation had simply said 3 reimbursement will be at AWP, you would have 4 concluded that the proper reimbursement rate was a 5 zero spread by statute. 6 A. No. 7 Q. Okay. 8 MR. EDWARDS: Now I want to mark as 9 Exhibit Hartman 039 a copy of a letter from Frank 10 Camozzi, chief of the technical issue section of 11 Medicare, to S. Stewart dated November 4, 1994, 12 the Bates stamps are HHC 015-1693 to 94. 13 (Two-page letter dated November 4, 14 1994, to Ms. S. Stewart from Mr. Camozzi marked 15 Exhibit Hartman 039 for identification.) 16 (Handing Exhibit Hartman 039 to the 17 witness.) 18 BY MR. EDWARDS: 19 Q. Have you ever seen this document before? 20 A. No. DMSO? Wow. 21 Q. Are you aware that the government has 22 made a significant production to the defendants in</p>

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1 this case of documents relating to this issue?
2 A. Which issue are we talking about here?
3 Do you mean the issue of --
4 Q. The issue of reimbursement under
5 Medicare.
6 A. I've had my staff review and told them
7 to review a variety of documents that fit within
8 certain guidelines. I don't remember them putting
9 -- bringing this to my attention or some of the
10 other -- I mean I don't know how substantial the
11 correspondence is, but I have not seen this.
12 Q. In the third paragraph of this letter,
13 Mr. Camozzi says, quote, "However, the Healthcare
14 Financing Administration, HCFA, has not yet
15 implemented the estimated acquisition cost portion
16 of this regulation or provided carriers with
17 specific instructions on how to execute this
18 segment of the drug payment policy."
19 Is that consistent with your
20 understanding?
21 A. As I say, my understanding was that the
22 surveys had not been done and the information had

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1 not been gathered, and if this is -- you know, if
2 this is an offshoot of that, you know, I didn't -
3 - I didn't know this -- this followed.
4 Q. Well, as of November 4, 1994, at least,
5 the EAC prong of the regulation on which you rely
6 had not been implemented; correct?
7 A. I am not sufficiently schooled in the
8 administrative law or whatever to make -- to make
9 any judgment from this letter one way or the
10 other. I mean that's something for a lawyer to
11 conclude.
12 Q. Do you know whether it had been
13 implemented as of 1995 or 1996?
14 A. Are we talking about have the surveys
15 been implemented, or are you talking about now
16 this acquisition portion of the regulation?
17 Q. I am talking about the estimated
18 acquisition cost portion of the regulation.
19 A. As I say, I've -- my understanding of
20 the regulations are as put forward in the footnote
21 we've been talking about. I had understood that
22 the surveys had not been done, and that's all I

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1 understood, and what that meant in terms of legal
2 implications, I do not know.
3 Q. So you didn't know that the estimated
4 acquisition cost portion of the regulation had not
5 been implemented?
6 A. I, you know, judging from this, I don't
7 know one way or the other. I don't know what that
8 means, "has not been implemented."
9 Q. Well, would it be fair to say that "has
10 not been implemented" means has not been
11 implemented?
12 A. Well, it would be fair to say the
13 following. That since no one had done any surveys
14 that I know of, no one knew what an estimated
15 acquisition cost was, so it -- whether -- so there
16 -- so that it would be impossible to implement
17 this particular section of CFR from '92 to '97 in
18 my footnote.
19 Q. Well, you said you base your
20 interpretation of the regulation on your
21 understanding of the English language. Is it
22 consistent with your understanding of the English

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1 language that the words "has not been implemented"
2 in this document means exactly what they say, has
3 not been implemented?
4 A. Well, I see -- I see this in re: HCPCS
5 code J 1212, injection of DMSO, and so I don't
6 know whether this is -- I don't -- this does not
7 seem to me to be a broad-based policy letter.
8 Maybe it is. I just -- I don't know. I can't tell
9 from this.
10 I don't -- if this were in re, you know,
11 the implications of estimating -- of estimated
12 acquisition cost portion, then I -- then I would
13 see a broader application. I don't know. It does
14 say that. But how broad -- broadly that went
15 through, all drug reimbursement -- I know there
16 were -- estimated acquisition costs were out
17 there. They could -- I mean there were
18 acquisition costs. One could estimate them. They
19 weren't -- Medicare wasn't doing it. So it be
20 would very hard to implement this calculation that
21 I have gone ahead and implemented.
22 Q. I take it you have never talked to

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1 anybody who worked at HCFA during this time period
2 in order to determine whether your interpretation
3 of the regulation is correct?

4 A. I have never talked to anyone at HCFA
5 about whether because the surveys had not been
6 done that essentially this phrasing is such that -
7 - that they -- that there was no estimated
8 acquisition cost. I would have to say that from
9 '98 through 2003 they went to the lower of the
10 actual bill -- actual charge, which by its nature
11 is an estimated acquisition cost, and there is
12 discussion in footnote 14 from CMS of what that
13 means, and so there was -- there was -- you know,
14 whether this, you know, average worked and how far
15 it went, there is still clearly some reliance on
16 acquisition costs, and as it was stated in the '98
17 through 2003 regulation.

18 So I haven't done -- I have taken -- I
19 have taken the CFR as it reads and assumed that
20 that was the guiding -- that was what was guiding
21 reimbursement.

22 Q. Well, you just stated that the law was

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1 changed in 1997 or 1998 to indicate that
2 reimbursement would be based on the lower of the
3 billed charge or 95 percent of AWP?

4 A. The actual charge or 95 percent of the
5 national AWP.

6 Q. And it is your testimony that the words
7 "actual charge" in that context refer to the
8 amount that the physician paid for the drug?

9 A. Well, it is not just my testimony. It
10 is the testimony of CMS. In footnote 14 I cite
11 Thomas Scully talking about how these types of
12 drugs would be reimbursed, "and by law, we
13 generally pay for these drugs based on the actual
14 charge or 95 percent of the AWP, whichever is
15 lower," which says to me it is -- the bill charges
16 the acquisition, whichever is lower, and Mr. Young
17 clarifies that further in the same footnote where
18 he says in his paragraph 170, "From 1992 to date,
19 moreover, reimbursement under Medicare Part B has
20 generally been made at the lower of the billed
21 charge amount or AWP through '97 or 95 percent of
22 AWP after '97. The carriers may reimburse at less

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1 than the AWP base rates where, for instance, the
2 physician's bill charges are less."

3 That is acquisition cost.

4 Now I mean maybe Mr. Young is wrong, and
5 maybe Mr. Scully is wrong, but I have -- this
6 entire notion of acquisition, bill charged, it has
7 been in that vein that I have seen it throughout
8 the Medicare regulations.

9 Q. How do you know that the phrase "billed
10 charge" does not refer to the charge that the
11 physician puts on the Medicare claim as opposed to
12 the price that the physician pays for the drug?

13 A. It is my reading of these particular
14 citations and other materials which I can't -- I
15 can't recall right now. I can try and look --
16 look at what those cites are.

17 Q. Are you prepared to stake your
18 reputation on that reading?

19 MR. SOBOL: Objection.

20 A. Stake my reputation?

21 Q. Your reading could be wrong; correct?

22 A. My reputation as a reader or as what? I

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1 am not -- I am not an expert in -- we know I am
2 not an expert in Medicare regulations, and I am
3 reading what some of your own experts have said,
4 and I'm reading what some of the CMS
5 representatives and -- let's see what it -- what
6 it is -- the CMS administrator has said, and I am
7 interpreting it in that way, and that's as --

8 Q. Well, what Mr. Scully and Mr. Young said
9 is not inconsistent with the interpretation that
10 "actual charge" refers to the charge that the
11 physician puts on the Medicare claim form as
12 opposed to the price that the physician pays for
13 the drug; correct?

14 A. It is my understanding that they were to
15 be one and the same.

16 MR. EDWARDS: What I am going to do is
17 mark as Deposition Exhibit Hartman 040 a copy of
18 42 CFR 405.517 revised as of October 1, 1999.
19 (42 CFR 405.517 marked Exhibit
20 Hartman 040 for identification.)

21 MR KAUFMAN: Excuse me, Steve. Is this
22 number Exhibit Hartman 040?

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<p style="text-align: right;">898</p> <p>1 THE REPORTER: Exhibit Hartman 040. 2 (Handing Exhibit Hartman 040 to the 3 witness.) 4 BY MR. EDWARDS: 5 Q. Have you seen Exhibit Hartman 040 6 before? 7 A. I think I have. 8 Q. You have actually looked at the 9 regulation? 10 A. Oh, yes. I have had copies of each of 11 these, the subsections. The boxed -- the boxed 12 portions, I have had my staff pull out the 13 specific wording that was applicable here, and at 14 times, I have looked at it more broadly, but. 15 Q. So let me direct your attention to 16 subsection B, which says "Methodology. Payment for 17 a drug or biological described in paragraph A of 18 this section is based on the lower of the actual 19 charge on the Medicare claim for benefits or 95 20 percent of the national average wholesale price of 21 the drug or biological." 22 Doesn't this demonstrate conclusively</p>	<p style="text-align: right;">900</p> <p>1 pointing to appears verbatim in my footnote 13 2 under the guiding regulations for 1998 through 3 2003, so it is -- it is clear that I have read 4 this. It is clear that I have taken this into 5 account. 6 I have looked at the, as I said, said 7 under footnote 14, additional testimony, and when 8 I see here that the defendants' expert Steven 9 Young has said that reimbursement under Medicare 10 Part B is generally made at the lower of the 11 billed charged amount, and that's what I am taking 12 to be the amount charged on the Medicare claim -- 13 Q. But billed by whom? 14 A. I am taking the billed charge on the 15 part of the physician to be the same as the billed 16 amount to the physician. 17 Q. Where does it say that? Where does it 18 say that the charge that the physician puts on the 19 Medicare claim form has to be the same as the 20 price that the physician paid to the manufacturer? 21 A. I have told you that this is based on my 22 broad -- broader reading of the documents in this</p>
<p style="text-align: right;">899</p> <p>1 that your interpretation of the statute is wrong? 2 MR. SOBOL: Objection. 3 A. No. 4 MR. SOBOL: Before we go ahead, I know 5 it is five o'clock. 6 Q. Doesn't this demonstrate conclusively 7 that the statute -- 8 MR. SOBOL: Hold on a second. Relax. 9 MR. EDWARDS: Excuse me? 10 MR. SOBOL: I know it is five o'clock. 11 Do you want to finish your questions on this 12 document? 13 MR. EDWARDS: Yes. 14 MR. SOBOL: Okay. 15 BY MR. EDWARDS: 16 Q. Doesn't this demonstrate conclusively 17 that the words "actual charge" was -- were 18 designed to reflect the charge that the physician 19 put on the claim for benefits as opposed to the 20 amount that the physician was charged by the 21 manufacturer? 22 A. The particular sentence that you are</p>	<p style="text-align: right;">901</p> <p>1 matter, conversions with our affiliates at the 2 Harvard School of Public Health regarding Medicare 3 types of reimbursement, and it is based on that 4 broad set of evidence. 5 Q. Did you read the legislative history of 6 the Balanced Budget Act in 1997 which gave rise to 7 this change in the Medicare reimbursement formula? 8 MR. SOBOL: Objection to the form. 9 A. It is my recollection I have read 10 portions of that, but I -- I -- I -- it's -- I'm 11 not certain. 12 Q. And are you aware of the fact that the 13 Clinton administration proposed to Congress that 14 reimbursement be based on the estimated 15 acquisition cost of the physician and Congress 16 rejected that? 17 MR. SOBOL: Objection. 18 A. I -- I am aware that there was -- there 19 was much disagreement among various stakeholders 20 in how reimbursement rates should be paid and 21 calculated, and we have been talking about it all 22 day.</p>

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1 Q. Are you aware of the fact that Congress
2 rejected EAC as a basis for reimbursement in the
3 Balanced Budget Act of 1997?

4 MR. SOBOL: Objection to the form. You
5 may answer.

6 A. I think I have cited -- I know that Mr.
7 Young has talked about that, and -- and so I -- I
8 am generally aware of -- that there has been that
9 debate and certain proposals have been rejected.

10 Q. And are you aware that that specific
11 proposal was rejected?

12 MR. SOBOL: Objection to the form.

13 A. I'm not aware of the specificity of
14 individual proposals being either rejected or
15 accepted.

16 MR. EDWARDS: At this point, I would
17 move on to some additional documents, Tom.

18 MR. SOBOL: Let's suspend for the day
19 and reconvene tomorrow morning at 9:30, which is
20 early for Mr. Hartman. That's why we're not
21 starting earlier.

22 MR. EDWARDS: He will be here at eight

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1 o'clock.

2 THE WITNESS: That is why I cannot take
3 breaks.

4 MR. KAUFMAN: He is superman. He doesn't
5 take breaks.

6 MR. SOBOL: Because he is late to work
7 every day.

8 THE VIDEOGRAPHER: The time is 5:08. The
9 deposition is suspended. This is the end of
10 cassette 4. We are off the record.

11 (Whereupon, at 5:08 p.m., the
12 deposition was adjourned.)

13

14

15

16 RAYMOND S. HARTMAN, Ph.D.

17 Subscribed and sworn to and before me

18 this _____ day of _____, 20____.

19

20

21

22 _____
Notary Public

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1 CERTIFICATE

2 Commonwealth of Massachusetts

3 Plymouth, ss.

4 I, Judith McGovern Williams, a Registered

5 Professional Reporter and Notary Public in and for the

6 Commonwealth of Massachusetts, do hereby certify:

7 That RAYMOND S. HARTMAN, PH.D., the witness

8 whose deposition is hereinbefore set forth, was duly

9 sworn by me and that such deposition is a true record

10 of the testimony given by the said witness.

11 IN WITNESS WHEREOF, I have hereunto set my

12 hand this _____ day of _____, 2006.

13

14

15

16 Judith McGovern Williams

17 Registered Professional Reporter

18 Certified Realtime Reporter

19 Certified LiveNote Reporter

20 Certified Shorthand Reporter No. 130993

21 My Commission expires:

22 April 2, 2010

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